IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA
PITTSBURGH

ERIC MIKULA, AN INDIVIDUAL; Plaintiff, vs. C.R. BARD, INC., A NEW JERSEY BUSINESS CORPORATION; AND BARD PERIPHERAL VASCULAR, INC., AN ARIZONA BUSINESS CORPORATION; Defendants,	)	2:21-CV-01307-MJH

OPINION AND ORDER

Plaintiff, Eric Mikula, brings the within action against Defendants, C.R. Bard Incorporated and Bard Peripheral Vascular Incorporated (collectively Bard), alleging damages and injuries because of a defective inferior vena cava (IVC) filter. Mr. Mikula's Amended Complaint alleges claims for Negligence-Negligent Design, Negligent Manufacturing, and Negligent Failure to Warn (Count I) and Negligent Misrepresentation (Count II). (ECF No. 19). Bard has filed a Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6). (ECF No. 20). The matter is now ripe for consideration.

Upon consideration of Mr. Mikula's Amended Complaint (ECF No. 19), Bard's Motion to Dismiss (ECF No. 20), the respective briefs (ECF Nos. 21, 22, and 24), and for the following reasons, Bard's Motion to Dismiss will be denied.

I. Background

Mr. Mikula alleges that, in 2008, he was implanted with a Bard G2 inferior vena cava ("IVC") filter (the "Filter") for pulmonary embolism prophylaxis after being seriously injured in a motor vehicle accident. (ECF No. 19 at ¶¶ 13-15). Mr. Mikula further avers that on or about

late-July 2020, he "began to experience lower back pain, tiredness in his lower extremities and shortness of breath on exertion." *Id*. at ¶ 16. A CT scan revealed "the presence of an IVC filter with a bilateral lower extremity clot burden extending from the IVC filter to the inferior vena cava and bilateral lower extremities." *Id*. at ¶¶ 14-15. Mr. Mikula underwent thrombolysis to remove the clot, had stents placed in his right and left common external iliac veins, and had the Filter removed. *Id*. at ¶¶ 20-22.

Mr. Mikula's original Complaint alleged claims for Negligence (Count I), Negligent Misrepresentation (Count II), Strict Liability under 402A (Count III), Strict Liability under 402B (Count IV), Strict Liability-Failure to Warn (Count V), Breach of Express Warranty (Count VI), Breach of Implied Warranty of Fitness for a Particular Purpose (Count VII), and Violations of the Unfair Trade Practice and Consumer Protection Law (UTPCPL) (Count VIII). (ECF No. 1-2). Following Bard's Motion to Dismiss on Mr. Mikula's original Complaint, the Court dismissed the negligent design and negligent manufacturing components of Count I, but denied Bard's Motion to Dismiss the negligent failure to warn component. (ECF No. 16). The Court also dismissed Counts II, III, IV, V, VI, VII, and VIII. Mr. Mikula was granted leave to amend his Count I, negligent design and negligent manufacturing claims, and his Count II, negligent misrepresentation claim. The Court dismissed the remaining claims with prejudice

In his Amended Complaint, Mr. Mikula has repleaded his Count I-negligent design, negligent manufacturing claims, and negligent failure to warn claim and his Count II-negligent misrepresentation claim. In their Motion to Dismiss, the Bard defendants seek dismissal of the Amended Complaint on the following grounds: 1. Mr. Mikula fails to state a plausible negligent design claim (Count I); 2. Mr. Mikula fails to state a plausible negligent manufacturing claim

(Count I); and 3. Mr. Mikula fails to state a plausible negligent misrepresentation claim (Count II)

II. Standard of Review

When reviewing a motion to dismiss, pursuant to Federal Rule of Civil Procedure 12(b)(6), the court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Eid v. Thompson*, 740 F.3d 118, 122 (3d Cir. 2014) (quoting *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir.2008)). "To survive a motion to dismiss a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556); *see also Thompson v. Real Estate Mortg. Network*, 748 F.3d 142, 147 (3d Cir. 2014). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. "Factual allegations of a complaint must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. A pleading party need not establish the elements of a *prima facie* case at this stage; the party must only "put forth allegations that 'raise a reasonable expectation that discovery will reveal evidence of the necessary element[s].'" *Fowler v. UPMC Shadyside*, 578 F.3d 203, 213 (3d Cir.2009) (quoting *Graff v. Subbiah Cardiology Associates, Ltd.*, 2008 WL 2312671 (W.D. Pa. June 4, 2008)); *see also Connelly v. Lane Const. Corp.*, 809 F.3d 780, 790 (3d Cir.2016) ("Although a reviewing court now affirmatively disregards a pleading's legal conclusions, it

must still . . . assume all remaining factual allegations to be true, construe those truths in the light most favorable to the plaintiff, and then draw all reasonable inferences from them.") (citing *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 154 n. 1 (3d Cir.2014)).

Nonetheless, a court need not credit bald assertions, unwarranted inferences, or legal conclusions cast in the form of factual averments. *Morse v. Lower Merion School District*, 132 F.3d 902, 906, n. 8 (3d Cir.1997). The primary question in deciding a motion to dismiss is not whether the Plaintiff will ultimately prevail, but rather whether he or she is entitled to offer evidence to establish the facts alleged in the complaint. *Maio v. Aetna*, 221 F.3d 472, 482 (3d Cir.2000). The purpose of a motion to dismiss is to "streamline [ ] litigation by dispensing with needless discovery and factfinding." *Neitzke v. Williams*, 490 U.S. 319, 326–327, (1989).

III. Discussion

A. Count I-Negligent Design

Bard argues that Mr. Mikula's negligent design claim should be dismissed because the Amended Complaint only contains conclusory and broad allegations. Bard contends that in dismissing Mr. Mikula's original design defect claim, this Court found that Mr. Mikula's allegations "fail to address either the design of Bard's product or the availability of safer, feasible alternatives in any level of meaningful detail." (ECF No. 16 at p. 6). Bard maintains that the Amended Complaint fails to correct these deficiencies and that nowhere does Mr. Mikula aver facts about Bard's alleged conduct, or how Bard may have failed to exercise reasonable care in designing, making, or selling the Filter.

Mr. Mikula maintains that he has sufficiently alleged a design defect. He contends Bard owed a duty to foreseeable users of their product to ensure the device was reasonably safe for its intended use. Mr. Mikula asserts that the IVC Filter was negligently designed in such a manner

that it was unsafe for use as a DVT prophylaxis in trauma patients, such as himself, who were otherwise not at risk for clots, and which caused such patients to experience clotting. He argues that defendants were negligent by failing to adequately test the Filter for use as a trauma prophylaxis, particularly when it knew or should have known it was being used extensively for this purpose.

In products liability claims sounding in negligence, Pennsylvania courts follow the Restatement (Second) of Torts. *Smith v. Howmedica Osteonics Corp.*, 251 F.Supp.3d 844, 852 (E.D. Pa. 2017). Negligent design claims are governed by § 398. *Lance v. Wyeth*, 624 Pa. 231, 85 A.3d 434, 445 n. 13 (2014). To plead a viable claim for negligent design, a plaintiff must plead facts to plausibly show that the defendant failed to exercise reasonable care in the adoption of a safe design. *Smith*, 251 F.Supp.3d at 854. "[T]he determination of whether a product was negligently designed turns on whether 'an alternative, feasible, safer design would have lessened or eliminated the injury plaintiff suffered.'" *Salvio v. Amgen, Inc.*, 810 F.Supp.2d 745, 754 (W.D. Pa. 2011) (citations omitted).

Here, Mr. Mikula alleges that Bard was negligent by designing and distributing a product which it knew or should have known had the likelihood of causing potential harm that exceeded the likelihood of potential harm from other similarly purposed and available IVC filters. He also alleges that Bard failed to use reasonable and prudent care in the design, research, manufacture, and development of Bard IVC Filters so as to avoid the risk of serious harm associated with their use. (ECF No. 19 at ¶ 68). Further, Mr. Mikula has alleged that, at the time of the design, Bard was aware that the IVC filters would be used by patients with special medical conditions, such as Mr. Mikula's, and that, in such circumstances, the Filters were less efficient than Bard's predicate device, known as SNF. Mr. Mikula alleges that the SNF filter had the same indication

for use, but with nearly zero adverse events. *Id*. at ¶¶ 46 and 66. Mr. Mikula has alleged that the IVC filter's design resulted in insufficient integrity and strength for the filter to withstand normal stresses within the human body to resist fracturing, migrating, tilting, and/or perforating the inferior vena cava. *Id*. at ¶ 49. Mr. Mikula further alleges that the IVC filter's design defects caused insufficient filter integrity and strength, and that the Bard's predicate filter, the SNF, offered an alternative, feasible, and safer design. Therefore, the Court is satisfied that the Amended Complaint presents a sufficiently plausible negligent design claim.

Accordingly, Bard's Motion to Dismiss Mr. Mikula's Count I negligent design claim will be denied.

B. Count I-Negligent Manufacturing

Bard next contends that Mr. Mikula's Negligent Manufacturing claim should be dismissed because the Amended Complaint is devoid of any facts regarding Bard's manufacturing process. Bard contends that Mr. Mikula's Amended Complaint fails to allege facts that plausibly suggest any failure to exercise reasonable care during the "manufacturing process." Bard also argues that Mr. Mikula's Amended Complaint fails to include any factual allegations about Bard's manufacturing, assembling, selling, supplying, approving, or distribution of the Filter other than the boilerplate conclusory assertion that Bard's negligence was the proximate cause of Plaintiff's alleged injuries. Bard specifically argues that this Court originally dismissed Mr. Mikula's Complaint, Count I, negligent manufacturing claim, where it concluded "[a]bsent any factual allegation as to the nature of any deficiencies in the manufacturing process, Mr. Mikula cannot state a claim for negligent manufacturing." (ECF No. 16 at p. 7). Thus, Bard seeks dismissal of Count I negligent manufacturing claim. Mr. Mikula contends that the Amended Complaint alleges that the filter was improperly manufactured and

caused him to experience extensive blood clotting, the exact condition it was intended to mitigate, and for which he had no personal or family history.

Negligent manufacturing claims are governed by Restatement (Second) of Torts § 395. *Lance,* 85 A.3d at 445 n. 13. To plead a viable negligent manufacturing claim, "it is necessary to allege some facts that would plausibly suggest that the manufacturer failed to exercise a reasonable standard of care during the 'manufacturing process.' " *Smith,* 251 F. Supp. 3d at 853.

Here, Mr. Mikula's Amended Complaint alleges manufacturing defects that include, but are not limited to, the existence of "draw markings" and circumferential grinding markings on the exterior of the surface of Bard IVC Filters compromised the structural integrity of the IVC Filter while in vivo. (ECF No. 19 at ¶ 50). Mr. Mikula avers that these markings, caused by the manufacturing process, made the IVC Filter more susceptible to fatigue, failure, and migration. *Id*. at ¶ 52. Mr. Mikula identifies deficiencies in the IVC Filter that were allegedly caused by the manufacturing process. Any further facts regarding the manufacturing process may be obtained through discovery. Therefore, the Court is satisfied that said allegations present a sufficiently plausible negligent manufacturing claim.

Accordingly, Bard's Motion to Dismiss Mr. Mikula's Count I negligent manufacturing claim will be denied.

C. Negligent Misrepresentation-Count II

Bard contends that Mr. Mikula's negligent misrepresentation claim fails because it is inadequately pleaded under the heightened pleading standards of Fed. R. Civ. P. 9(b) and/or under the general pleading standards of Fed. R. Civ. P. 8. Bard also argues that Mr. Mikula fails to plead sufficient facts to establish that Bard made any misrepresentation to Plaintiff's prescribing physician. Bard argues that, as in Mr. Mikula's original Complaint, his Amended

Complaint does not plead facts to support his negligent misrepresentation claim. Bard contends that Mr. Mikula only pleads generalities, with no alleged factual details as to who, what, when, where, and why any alleged misrepresentations were made. Furthermore, Bard argues that the Amended Complaint contains no allegation explaining what false representation was made to Mr. Mikula's prescribing physician or that said physician relied upon any such representation. Mr. Mikula responds and generally argues that his Amended Complaint sufficiently pleads his claim.

Under Pennsylvania law, to prove negligent misrepresentation, a plaintiff must prove "(1) a misrepresentation of a material fact; (2) made under circumstances in which the misrepresenter ought to have known of its falsity; (3) with an intent to induce another to act on it; and (4) which results in injury to a party acting in justifiable reliance on the misrepresentation." *Bortz v. Noon*, 556 Pa. 489, 729 A.2d 555, 561 (Pa. 1999) (citing *Gibbs v. Ernst*, 538 Pa. 193, 647 A.2d 882, 890 (Pa. 1994)).

Federal Rule of Civil Procedure 9(b) states, "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). The United States Court of Appeals for the Third Circuit has noted that Rule 9(b) "requires plaintiffs to plead with particularity the 'circumstances' of the alleged fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges." *Kester v. Zimmer Holdings, Inc.*, Civ. No. 2:10-CV-00523, 2010 WL 2696467, *12 (W.D. Pa. June 16, 2010) (quoting *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984)).

Here, the Amended Complaint alleges that "information Bard distributed to the public, the medical community, and Plaintiffs was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, and instructions for use, as well as through their officers, directors, agents, and representatives." (ECF No. 19 at ¶ 76). Said communications allegedly conveyed that "Bard IVC Filters were safe and fit when used for their intended purpose or in a reasonably foreseeable manner; that they did not pose dangerous health risks in excess of those associated with the use of other similar IVC filters; that any and all side effects were accurately reflected in the warnings; and that they were adequately tested to withstand normal placement within the human body." *Id*. at ¶ 77. Therefore, the allegations contain the sufficient requisite specificity to place Bard on notice of the precise misconduct with which it is charged. After careful review of the Amended Complaint, at this stage, Mr. Mikula has sufficiently alleged facts of a misrepresentation of facts to support his negligent misrepresentation claim.

In order to establish justifiable reliance, Mr. Mikula must plead that his health care providers relied upon Bard's representations and omissions when they implanted the filter. *See Burton v. Danek Med., Inc.*, No. 95-5565, 1999 WL 118020, at *6 (E.D. Pa. Mar. 1, 1999). The Amended Complaint alleges that Mr. Mikula's health care providers relied upon the false and negligent misrepresentations and omissions made by Bard, which induced them to use Bard IVC Filters. (ECF No. 19 at ¶ 83). Further, it alleges that Mr. Mikula's health care providers would not have prescribed and implanted Bard IVC Filters if the true facts had not been concealed and mispresented by Bard. *Id*. at ¶ 84. Therefore, justifiable reliance has been sufficiently pleaded.

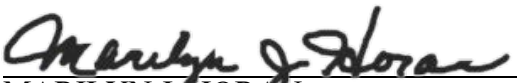
Accordingly, Bard's Motion to Dismiss, as regard Count II, will be denied.

ORDER

Following consideration of the foregoing, Bard's Motion to Dismiss is denied. Bard shall file its Answer on or before March 29, 2022.

DATED this 15th day of March, 2021.

BY THE COURT:



MARILYN J. HORAN
United States District Judge